



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR       | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------------|---------------------|------------------|
| 09/884,629      | 06/19/2001  | Peter H. St. George-Hyslop | 1034/IJ800US1       | 3866             |

7590

06/16/2005

DARBY & DARBY P.C.  
805 Third Avenue  
New York, NY 10022

EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/884,629

Applicant(s)

ST. GEORGE-HYSLOP ET AL.

Examiner

Joseph T. Weitach

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 March 2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 is/are pending in the application.  
4a) Of the above claim(s) 8-23 and 29-35 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-7, 24-28 is/are rejected. <sup>1-7, 4-7</sup> 90  
7) ☐ Claim(s) 3 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

Art Unit: 1632

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 23, 2005 has been entered.

**DETAILED ACTION**

This application filed June 19, 2001, claims benefit to provisional application 60/212,534, filed June 20, 2000.

Applicants amendment filed March 23, 2005, has been received and entered. No new amendments have been filed. Claims 1-35 are pending.

***Election/Restriction***

Applicant's election with traverse of Group I, claims 1-7, 24-28, filed February 21, 2003, in Paper No. 9 was acknowledged. No new arguments have been provided, therefore the restriction is maintained for the reasons of record. The requirement is still deemed proper and is therefore FINAL.

This application contains claims drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Art Unit: 1632

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 1-35 are pending. Claims 8-23, 29-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9. Claims 1-7, 24-28 are currently under examination as they are drawn to a transgenic non-human mammal whose genome comprises a polynucleotide that encodes an amyloid precursor protein 695 transgene wherein the protein produced has the specific mutations in residues 670, 671 and 717 of APP<sub>695</sub>.

### ***Claim Rejections - 35 USC 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 2, 4-7, 24, 25, 27 and 28 rejected under 35 U.S.C. 102(e) as being anticipated by Sommer *et al.* (US Patent publication 2001/0016951 A1) is withdrawn.

Art Unit: 1632

As indicated in the advisory action, Applicants arguments were found persuasive. Specifically, Sommer *et al.* fail to teach each and every limitation of the claimed invention.

Claims 1, 2, 4-7 and 24- 28 stand rejected under 35 U.S.C. 102(e) as being anticipated by Hsiao *et al.* (US Patent 6,509,515).

Applicants summarize the requirements of making a rejection under 35 USC 102 (page 9) and argue that while Hsiao *et al.* teach the known mutations, it fails to provide all the limitations of having each of the mutations as instantly claimed (pages 9-10). See Applicants' amendment, top of pages 9-10. Applicants' arguments have been fully considered, but not found persuasive.

As noted previously, the review of Hsiao *et al.* indicates that all three mutations were known in the prior art and contemplated for use in generating transgenes for use transgenic models. Moreover, as noted in the specification, the specific combination of the three mutations were reduced to practice in the prior art , albeit with a different form of APP(page 11). While the instantly claimed transgenic animal was not reduced to practice by Hsiao *et al.*, this does not overcome the fact that Hsiao *et al.* provide the necessary teachings to generate the claimed transgenic animal.

Any arguments regarding an unexpected results have not been considered persuasive because the MPEP indicates that unexpected results can not overcome anticipation in a rejection made under 35 USC 102. It is noted that without the reduction to practice and the unpredictability of the art of transgenics, the specific outcome/phenotype can not be predicted precisely, however in view of the art of Alzheimer's Disease as a whole, there would be a general expectation that greater amounts of alterations associated with the disease would result in a more

Art Unit: 1632

dramatic phenotype. Moreover, the unexpected phenotype is only demonstrated when expression is affected by one promoter and only in the mouse. In this case, consistent with Applicant's remarks concerning the art of transgenics, the unexpected results would not extend to the use of any promoter and expression in any non-human mammal encompassed by the instant claims. However, as discussed above this is not found persuasive because each of the cited reference teaches that this APP mutation was known and contemplated for use in generating transgenic animal models of Alzheimer's Disease.

### ***Conclusion***

No claim is allowed.

As indicated previously, claim 3 is free of the art of record because while the art provides various genetic backgrounds for the resulting transgenic mice produced, none specifically teach any specific reason to generate (C3H x C57BL6) x C57 cross.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1632

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

*Joe Woitach*  
AU 1632